ORIGINAL REPORT: EPIDEMIOLOGIC RESEARCH

Cognitive Behavioral Therapy for Children with Dental Anxiety: A Randomized Controlled Trial

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Abstract: *Dental anxiety affects approximately 9% of children and is associated with poor oral health, pain, and psychosocial problems. The objective of this study was to investigate the efficacy of cognitive behavioral therapy (CBT) for children with dental anxiety in specialist pediatric dentistry. The study used a parallel-group superiority randomized controlled trial design. The primary outcome measure was the behavioral avoidance test; assessors were blind to treatment allocation. Participants were 8 boys and 22 girls 7 to 18 y old (mean ± SD, 10 ± 3.1). Children fulfilling the diagnostic criteria for dental anxiety were randomized to CBT (*n *= 13) or treatment as usual (*n *= 17), such as various sedation methods. Psychologists provided 10 h of CBT based on a treatment manual. Treatments were conducted in a naturalistic real-world clinical setting. Assessments were conducted before the treatment, 3 mo after the start of treatment, and at 1-y follow-up. The analyses of the primary outcome measure by repeated-measures analysis of variance and independent t test showed that children receiving CBT made superior, statistically significant improvements at follow-up (16.8 ± 2.4) compared with treatment as usual (11.4 ± 3.1, P < 0.01). A large between-group effect size (Cohen's d = 1.9) was found. Following treatment, 73% of those in the CBT group managed all stages of the dental procedures included in the behavioral avoidance test compared with 13% in the treatment-as-usual group. Furthermore, 91% in the CBT group compared with 25% in the treatment-as-usual group no longer met the diagnostic criteria for dental anxiety at the 1-y follow-up according to the secondary outcome measure. Measures of dental anxiety and self-efficacy showed larger improvements in the CBT group compared with controls. We conclude that CBT is an efficacious treatment for children and adolescents with dental anxiety and should be made accessible in pediatric dentistry (ClinicalTrials.gov: NCT01798355).*

Knowledge transfer statement: *The results of this study can be used by decision makers and clinicians when planning to implement evidence-based treatment in pediatric dentistry and give children and adolescents access to methods for treating dental anxiety. The results can also be used by parents of children with dental anxiety when asking dentists to cooperate with psychologists using cognitive behavioral therapy.*

Keywords: pediatric dentistry, clinical psychology, self-efficacy, evidence-based dentistry, dental fear, behavioral problem

Introduction

Dental anxiety affects approximately 9% of children and adolescents (Klingberg and Broberg 2007). The fourth edition text revision of the *Diagnostic and Statistical Manual of Mental Disorders* (*DSM-IV-TR*) classifies dental anxiety as a form of specific phobia (American Psychiatric Association [APA] 2000). The

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condition is characterized by marked fear and anxiety response when the individual is exposed to dental care. It leads to intense distress and/or avoidance (APA 2000). Dental anxiety often manifests itself during childhood and is associated with poor oral health such as untreated caries, missing teeth, or periodontal problems (Crego et al. 2014). These negative consequences also include sense of embarrassment related to poor oral health, reduced self-confidence, and increased absence from work (Wide Boman et al. 2013).

Pediatric dentistry commonly employs several methods to deal with dental anxiety, which include tell-show-do, premedication with midazolam, nitrous oxide sedation, and general anesthesia (Klingberg et al. 2010; Roberts et al. 2010). A recent systematic review, however, reported that the quality of the evidence supporting these common methods in pediatric dentistry is low or very low (Mejàre et al. 2015). So it is uncertain whether these strategies influence behavioral problems sufficiently.

Cognitive behavioral therapy (CBT) has been shown to be effective for treatment of several specific phobias (Ollendick and King 1998; Antony and Barlow 2002). Moderate to large treatment effects for adults with dental anxiety have been observed in randomized trials (Kvale et al. 2004; Haukebø et al. 2008). CBT is a structured and brief psychological treatment based on a combination of psychoeducation, exposure, and homework exercises (Öst and Clark 2013). In qualitative studies, children and parents have reported positive experiences with CBT and have found CBT to improve their ability to deal with dental anxiety and other specific phobias (Svensson et al. 2002; Shahnavaz et al. 2015). The literature stresses the need for further research on the application of CBT in pediatric dentistry (Porritt et al. 2012).

Materials and Methods

Participants

A dental assistant called all parents whose children had been referred to 2 pediatric dental clinics in Stockholm from January 2013 through March 2014 for dental anxiety or behavioral management problems to invite them to participate in the study. Information about the study was sent to both private and public dental service clinics in Stockholm and published on the official web page of the Department of Dental Medicine at Karolinska Institutet, and local newspapers published articles about the trial. Self-referral was not allowed, so all potential participants were referred from a dentist in general dentistry.

Participants had to meet the following inclusion criteria: 1) the patient and all primary caregivers agreed to participate in the study, 2) the patient had a principal diagnosis of specific phobia (dental anxiety or intraoral injection phobia) according to the *DSM-IV-TR*, 3) no other psychiatric or developmentally related diagnoses considered to be the primary diagnosis, 4) the patient was not receiving concurrent psychological treatments and did not have appointments for psychological examination elsewhere, and 5) the patient needed dental care but not emergency care.

In addition to the eligibility criteria above, parents and children needed to fulfill some practical requirements for participation. They had to have 1) the time and opportunity to take time off from school to go to a specialist clinic for treatment, 2) a stable living situation with no family crisis such as an ongoing divorce, 3) no serious somatic illness that would disrupt daily life and hinder participation in the study, 4) access to a computer at home or in a public place for answering the online questionnaires related to the study, and 5) motivation to participate in the treatment.

Interventions

We based this trial on CBT models for treating anxiety disorders and specific phobias (Lyneham et al. 2003; Beidas et al. 2010; Davis et al. 2012). Our research team developed the therapist manual, 40 pages in total.

The patients, parents, and therapists met for 10 h of CBT at 2 pediatric dental clinics in Stockholm. Sessions 1 to 2, 3 to 4, and 5 to 6 were offered during the first 3 wk. Double sessions were offered at the same day with 15 min of rest between the sessions. Sessions 7 to 10 were offered during the remaining 8 wk (1 session/h every other week). The central components of these sessions were behavioral analyses, psychoeducation, parent education, exposure to dental procedures both in vivo and in films, relaxation techniques, procedural pain management information, and cognitive restructuring (Table 1). Patients underwent exposures by watching short films showing a child going through various dental procedures during the sessions with psychologist. Children and parents had access to dental tools and materials such as a probe, cotton balls, topical anesthetic, a spiral-shaped suction nozzle, and needle to practice at home. The manual and films are available in Swedish and can be obtained by emailing the corresponding author. Treatment was adapted to the child's age, and the younger the child, the more parental support and behavioral techniques (less cognitive interventions). The therapists conducting the treatment were 3 licensed psychologists with at least 5 y of psychology training at university and 1 y of clinical training under supervision. All therapists had a CBT qualification and between 6 mo and 8 y of experience delivering CBT in pediatric dentistry. To increase treatment adherence and therapist competence, the psychologist with 8 y of experience gave weekly supervision to the other 2 therapists during the study. Treatment fidelity was continuously discussed during these supervisions. The therapists were also given access to checklists for each session (maintaining the major feature of the session). The total number of dental visits varied depending on the patient's dental treatment needs. Dental treatment began earliest after session 6 in the CBT group. The treatment as usual consisted of methods such as, tell-show-do, distraction, premedication with midazolam, nitrous oxide sedation,

Table 1.
Description of Session Content.

1. Behavior analysis, psychoeducation (mechanisms of anxiety and cognitive behavioral therapy), introduction, and home assignments
2. Parent education (parents' relation to dentistry and fear, reinforcement/rewarding strategies, how to enhance children's self-efficacy)
3. Exposure list, goal setting, exposure, and controlled breathing
4. Exposure and cognitive restructuring
5. Exposure and pain management education, relaxation, and mindfulness training
6. Exposure, dentistry-related communication and social skill training, assertiveness, managing safety behavior, and preparation for meeting with dental staff
7. Exposure, evaluation of meeting with dental staff, preparation of dental treatment and repetition of goals, and relaxation and breathing techniques
8. Exposure and coping strategies and evaluation of exposure/treatment with dentist
9. Evaluation of dental treatment experiences and exposure and repetition
10. Evaluation of dental treatment experiences, relapse prevention plan, and diploma

and general anesthesia. Appendix A (available online) describes treatment as usual in more detail.

Objective

The objective of this study is to test the hypothesis that CBT for children and adolescents with dental anxiety is more efficacious than treatment as usual (behavioral management and sedation techniques) for increasing a child's ability to undergo dental procedures and reducing dental anxiety.

Outcomes

Primary outcome measure

The Behavioral Avoidance Test (BAT) was used in an earlier study of CBT for adults with dental anxiety (Haukebø et al. 2008). The version of the BAT used in this study was adapted to pediatric dentistry and more standardized than the earlier version. During the test, a dentist would expose participants to a potential maximum of 18 hierarchically organized dental clinical situations such as entering the dental treatment room, opening the mouth, injection of local anesthesia (a quarter of a cartridge), and drilling (a small piece of composite was etched to the buccal surface of a mandibular molar, which made it possible to simulate drilling in a tooth. This piece of composite was thereafter removed). Children were instructed by the dentist to try their best to complete the list of different dentistry procedures but were also given the possibility to discontinue at any moment (without being persuaded by parents or dentists to continue). The score for each child was sum of stages from 0 (not entering the dentist room) to 18 (managing the drill), 1 point for each stage. Measurement fidelity was ensured through detailed test manual and assessor training. A psychologist monitored and maintained the measurement fidelity by continuous discussions with dentists and dental assistants conducting the BAT. The Swedish BAT and its manual are available on request. The assessments were conducted before the treatment, 3 mo after the treatment, and at 1-y follow-up.

Other Outcome Measures

The secondary outcome measure was the presence or absence of dental anxiety as measured in the Structured Clinical Interview for Dental Anxiety (SCI-DA). The interview format was based on the specific phobia section of the Development and Well-Being Assessment (DAWBA) with additional questions related to dentistry. The reliability of DAWBA expert diagnoses has been reported as satisfactory (Aebi et al. 2012).

The other outcome measures were the child (CFSS-DS-C) and parent (CFSS-DS-P) versions of the Children's Fear Survey Schedule–Dental Subscale (CFSS-DS). The CFSS-DS has high test-retest reliability and validity (Klingberg 1994). The CFSS-DS consists of 15 items (scale 1–5, from no fear to high fear) measuring the degree of fear associated with various situations in dental and medical care and interactions with people unfamiliar to the child. We also used the Self-Efficacy Questionnaire for Specific Phobias (SEQ-SP). It consists of 14 questions (scale 1–5, from low to high self-efficacy) assessing the level of self-efficacy, defined as people's belief in their ability to accomplish given achievements (Bandura 1977). Preliminary evidence for the reliability and validity of the SEQ-SP has been demonstrated by Flatt and King (2009).

Sample Size

A dental assistant called the parents of 182 patients to recruit them to the study. The parents of 67 expressed interest in their child participating. Of these, 30 fulfilled the inclusion criteria and were randomized (Fig.). The sample size and power of this study are comparable to other studies of CBT and dental anxiety (Kvale et al. 2004; Haukebø et al. 2008).

Randomization

We used unrestricted randomization. An external person, not involved in the study, randomly assigned the participants to the treatment conditions according to a true randomization list that was generated at www.random.org. We allocated patients to the intervention groups only after deciding whether to include the patient in the study. Participants were randomly assigned to CBT (n = 13) or treatment as usual (n = 17). Participants were 8 boys and 22 girls 7 to 18 y old (mean ± SD, 10 ± 3.1). Table 2 presents the sociodemographic and clinical characteristics of the participants in the intervention groups.

Table 2.
Baseline Demographic and Clinical Characteristics.

Variable	CBT (n = 13)	TAU (n = 17)
Age, mean ± SD, y	10 ± 3	10 ± 3
Sex (female), %	70	76
Parental or sibling dental fear, %	31	30
Child born in Sweden, %	77	82
Parent 1 born in Sweden, %	70	71
Parent 2 born in Sweden, %	85	76
Parent 1 employed, %	62	88
Parent 2 employed, %	85	71
Clinical characteristics		
Comorbidity, %	8	12
Duration of dental anxiety, mean ± SD, y	4 ± 3.9	3.6 ± 2.9
Intraoral injection as main fear, %	76	71
Need for restorations, % Number of decayed surfaces, mean ± SD	69 1.8 ± 2.1	77 1.5 ± 1.2
Referred for extraction, % Number of extractions, mean ± SD	39 0.8 ± 1.1	35 0.4 ± 0.5

Comorbidity diagnoses are specific phobia for dogs in the CBT group and attention-deficit/hyperactivity disorder and social anxiety in the TAU group.
CBT, cognitive behavioral therapy; TAU, treatment as usual.

Blinding

The outcome assessors (for the primary outcome) were blind to the assigned treatment. At follow-up, to analyze the integrity of the blinding, we asked dentists to guess the allocation status of each participant in conjunction with administering the BAT. We also asked dentists whether they had learned the treatment status of any of the participants before they met them. Moreover, when scheduling the BAT, we instructed all participants and their parents not to mention which intervention they had received.

Procedure

All participants and parents (one parent if there was only one primary caregiver) provided written informed consent. The language of the study and all outcome measures was Swedish. We conducted assessments for all the outcome measures before treatment, after 3 mo of treatment, and at a 1-y follow-up. Except for the BAT and SCI-DA, all assessments used online questionnaires. Parents and children (older than age 11 y) were given access to the DAWBA on the Internet by personalized password (www.dawba.net). The clinical psychologist determined whether the patient met the inclusion criteria based on the face-to-face SCI-DA and DAWBA. Both the child and parent were interviewed using the SCI-DA. Three licensed psychologists with training in administering the SCI-DA and the DAWBA made the clinical assessments. During the recruitment period, these assessors received supervision on a regular basis from an expert in assessment of anxiety disorders in children and adolescents. The Regional Ethics Review Board in Stockholm approved the study, and the trial was registered at ClinicalTrials.gov (NCT01798355).

Statistical Analyses

Analyses used SPSS version 22 (SPSS, Inc.).

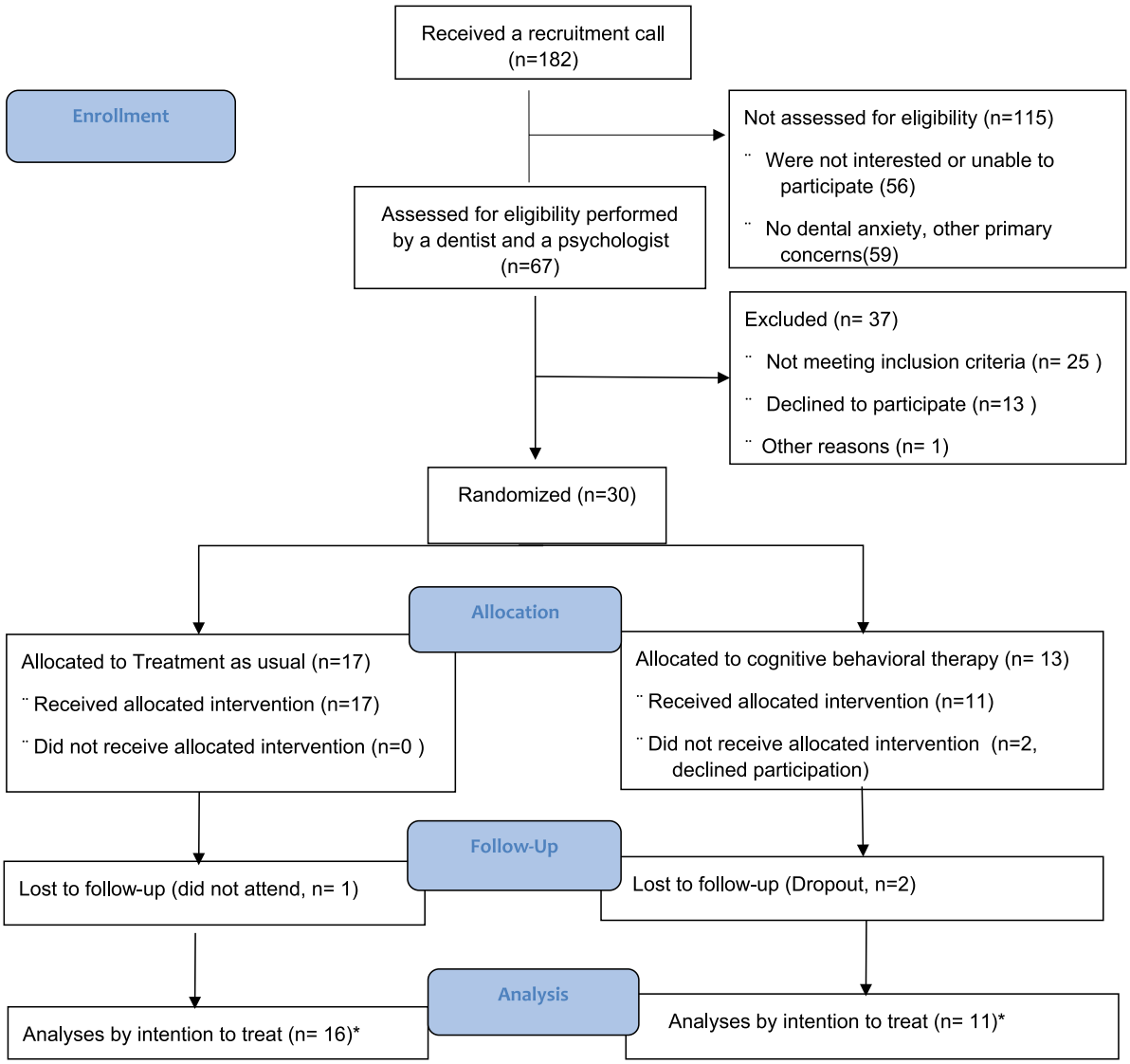
Data for the primary outcome measure, BAT, and other continuous measures, CFSS-DS and SEQ-SP, were analyzed by repeated-measures analysis of variance (ANOVA). Independent t tests were used to compare the CBT and control group before treatment, after treatment, and at the 1-y follow-up. Furthermore, paired t tests were used for the primary outcome measure and other continuous measures to analyze the within-group effects by comparing changes from before the treatment to after treatment, before treatment to the 1-y follow-up, and after treatment to the 1-y follow-up in each group. Cohen's d based on pooled standard deviations was used as a measure of effect size. The evaluation of the secondary outcome measure, SCI-DA (frequency of diagnosis-free patients in each group), and the clinically significant improvement for CBT and controls (between-group differences) were conducted by the chi-squared test or Fisher's exact test. Within-group differences in the secondary outcome measure (number of diagnosis-free children) were analyzed by Cochran's Q test and McNemar's test, exploring if there were within-group differences in the dichotomous dependent variable (before treatment to after, before treatment to the 1-y follow-up, and after treatment to the 1-y follow-up).

Results

Participant Flow and Attrition

The Figure shows the flow of participants through the trial. Two participants in the CBT group dropped out after randomization and before receiving treatment. In the first case, the parent reported that the child had received treatment during travel abroad due to an acute need for treatment and

Figure. Flowchart showing patient selection, randomization, dropout, and follow-up assessments.



* Applies to primary outcome measure

required no further dental treatment. In the second case, a parent got a new job and stated the child could not participate because the parent had difficulties taking time off to visit the clinic during office hours. Also, despite several reminders, 1 parent and child in the treatment-as-usual group did not complete the CFSS-DS and SEQ-SP after treatment, and another participant in the control group did not show up for the 1-y follow-up visit and measurement. Furthermore, parental outcome for 1 teenager among controls could not be obtained. One young participant (CBT group) had major difficulties understanding and answering the self-efficacy questionnaire, and we made the decision in consultation with the assessor not to include scores for the SEQ-SP. All other patients in both groups completed their treatments and measurements. Information from dental records showed that the necessary dental treatment needs for participants were met in both intervention groups. In the CBT group, 9% of participants (1 person) needed adjunctive midazolam sedation. In the treatment-as-usual group, 50% of participants were treated using nitrous oxide, midazolam, or general anesthesia.

Primary Outcome (Clinician Administered)

There was a statistically significant interaction of group and time in the ability to cope with dental procedures according to the BAT, the primary outcome measure, $F(2, 50) = 5.78$,

Table 3.
Efficacy of Cognitive Behavioral Therapy for Children with Dental Anxiety.

Measures (Scale Range), Group, and Participants	Before Treatment, Mean (SD)	After Treatment, Mean (SD)	1-y Follow-up, Mean (SD)	*F* Value (*df*)
BAT (0–18)				
CBT	7.0 (4.1)	15.2 (4.1)***	16.8 (2.4)**	G: 12.1 (1)**
n	13	11	11	T: 46.9 (2)****
TAU	7.2 (3.8)	11.1 (2.1)	11.4 (3.1)	I: 5.8 (2)***
n	17	17	16	
CFSS-DS-C (15–75)				
CBT	38.3 (11.6)	21.1 (6.5)*	24.7 (10.0)**	G: 15.4 (1)***
n	13	11	11	T: 20.5 (2.48)****
TAU	42.1 (9.5)	33.3 (9.7)	33.8 (7.6)	I: 0.96 (2.48)
n	17	16	16	
CFSS-DS-P (15–75)				
CBT	34.6 (7.6)*	21.2 (6.9)***	20.5 (4.9)**	G: 22.9 (1)****
n	13	11	11	T: 28.9 (2)****
TAU	40.8 (8.0)	34.3 (8.2)	30.7 (7.6)	I: 1.7 (2)
n	16	15	15	
SEQ-SP (0–70)				
CBT	35.0 (10.7)	53.1 (8.3)**	50.4 (7.8)**	G: 31.5 (1)****
n	12	10	10	T: 8.5 (2)**
TAU	29.4 (9.8)	32.0 (10.4)	32.6 (11.9)	I: 3.1 (2)
n	17	15	16	

BAT, behavior avoidance test; CBT, cognitive behavioral therapy; CFSS-DS-C, Child Fear Survey Schedule–Child Version; CFSS-DS-P, Child Fear Survey Schedule–Parental Version; G, group; I, interaction; SEQ-SP, Self-Efficacy Questionnaire for Specific Phobias; T, time; TAU, treatment as usual.
*$P < 0.05$. **$P \leq 0.01$. ***$P < 0.001$. ****$P < 0.0001$. Note that significance after treatment and at the 1-y follow-up is based on analyses with independent *t* tests.

$P = 0.006$, partial $\eta^2 = 0.19$. The mean values of ability to manage dental procedures according to the BAT indicate that children and adolescents improved more in the CBT group than controls (Table 3). Analyses of BAT results showed that children receiving CBT made superior, statistically significant improvements compared with controls both after the treatment (mean ± SD, 15.2 ± 4.1 for the CBT and 11.1 ± 2.1 for the controls) and at the 1-y follow-up (16.8 ± 2.4 for CBT and 11.4 ± 3.1 for controls). There was also statistically significant within-group improvement in the BAT (Table 4).

Effect size

A large between-group effect size (Cohen's $d = 1.4$ after the treatment and 1.9 at the 1-y follow-up) was found. Even the within-group effect sizes were large (Table 4).

The maximum value of 18 on the BAT means that patients can manage injection with local anesthesia and drilling in a composite placed on a tooth, procedures highly significant in a clinical context. Therefore, to calculate the clinical significance, we dichotomized the BAT values based on the cutoff value of 18. In the CBT group, 64% managed all stages in the BAT after treatment compared with 6% in the treatment-as-usual group. Corresponding frequencies at the 1-y follow-up were 73% and 13%, respectively. We found statistically significant improvement in favor of CBT at both the after-treatment assessment ($P = 0.002$) and 1-y follow-up ($P = 0.003$).

Assessment of masking

We found no significant association between the assessors' guess and the actual treatment allocation when

Table 4.
Effect Sizes of Cognitive Behavioral Therapy and Treatment as Usual for Dental Anxiety.

	Between-Group Effect Sizes Cohen's *d* (95% Confidence Interval)		Within-Group Effect Sizes Cohen's *d* (95% Confidence Interval)		
Measures (Scale Range)	After Treatment	1-y Follow-up	Before Treatment to after Treatment	Before Treatment to 1-y Follow-up	After Treatment to 1-y Follow-up
BAT	1.4 (0.5 to 2.25)	1.9 (0.95 to 2.9)			
CBT			2.0 (1.1 to 2.9)****	2.9 (0.8 to 5.0)****	0.5 (0.3 to 1.3)
TAU			1.3 (0.3 to 2.3)**	1.2 (0.4 to 2.0)***	0.1 (–0.5 to 0.8)
CFSS-DS-C	1.4 (0.5 to 2.3)	1.0 (0.2 to 1.9)			
CBT			1.8 (0.9 to 2.8)****	1.3 (0.3 to 2.3)***	–0.4 (–1.4 to 0.5)
TAU			0.9 (0.2 to 1.7)**	1.0 (0.2 to 1.7)**	–0.1 (–0.7 to 0.5)
CFSS-DS-P	1.7 (0.7 to 2.7)	1.5 (0.6 to 2.5)			
CBT			1.8 (0.7 to 3.0)****	2.2 (1.1 to 3.3)****	0.1 (–0.5 to 0.8)
TAU			0.8 (0.3 to 1.3)***	1.3 (0.3 to 2.3)***	0.5 (–0.3 to 1.2)
SEQ-SP	2.2 (1.1 to 3.3)	1.7 (0.7 to 2.6)			
CBT			1.9 (1.3 to 2.5)****	1.6 (0.2 to 3.1)**	–0.3 (–1.5 to 0.8)
TAU			0.3 (–0.4 to 0.9)	0.3 (–0.4 to 1.1)	0.1 (–0.7 to 0.8)

BAT, behavior avoidance test; CBT, cognitive behavioral therapy; CFSS-DS-C, Child Fear Survey Schedule–Child Version; CFSS-DS-P, Child Fear Survey Schedule–Parental Version; SEQ-SP, Self-Efficacy Questionnaire for Specific Phobias; TAU, treatment as usual.
**$P \leq 0.01$. ***$P < 0.001$. ****$P < 0.0001$. Note that significance is based on analyses with paired *t* tests.

evaluating the blinded behavioral avoidance test at follow-up. Moreover, all dentists reported that they were unaware of the allocation status of the patients before testing.

Secondary Outcomes (Clinician Administered)

At the after-treatment assessment and 1-y follow-up, there was a statistically significant between-group difference in the proportion of participants meeting the diagnostic criteria for dental anxiety according to the SCI-DA. After treatment, 64% of participants in the CBT group no longer met the diagnostic criteria for dental anxiety compared with 18% in the treatment-as-usual group. The corresponding changes at 1-y follow-up were 91% and 25%. The association between treatment and frequency of diagnosis-free patients in the CBT group was statistically significant at the after-treatment assessment ($P = 0.02$) and 1-y follow-up ($P = 0.001$).

The statistically significant and high percentage of participants in the CBT group not meeting the diagnostic criteria for dental anxiety at the after-treatment assessment and follow-up measurement can be considered evidence of clinically significant improvement.

Other Outcome Measures (Self-Reported and Parent Reported)

Analyses of the interaction between the intervention and time in the CFSS-DS-C, CFSS-DS-P, and SEQ-SP using repeated-measures ANOVA showed no statistically significant interaction (Table 3). However, we observed statistically significant between-group differences favoring CBT (reduction of fear and increased self-efficacy) at both the after-treatment assessment and 1-y follow-up for all 3 measures. The within-group improvements were significant for the CFSS-DS (C&P) in both groups but only significant in the CBT group for SEQ-SP.

Effect size

Large between-group effect sizes were observed for these measures. However, the within-group effect size for the SEQ-SP in the control group was low (Table 4).

To be able to evaluate a patient-specific and clinically significant fear, we chose either item 3, which measures injection fear, or item 8, which measures fear of drill for each participant and parent on the CFSS-DS. We selected whichever of these items the patient rated highest at the first assessment before the treatment. We designated a CFSS-DS score of 2 (little afraid) or less on a scale of 1 to 5 to indicate the cutoff for clinically significant improvement, and we categorized values between 3 and 5

as indicating no improvement. We then dichotomized the results according to the cutoff value. There was a statistically significant association between treatment and item values in favor of the CBT group after treatment for the CFSS-DS-C ($P = 0.010$) and the CFSS-DS-P ($P = 0.020$). Results for significant improvement at the 1-y follow-up were similar to after-treatment assessment results ($P = 0.001$, $P = 0.043$). In the CBT group, 73% of children showed a clinical improvement compared with only 6% of children in the control group after treatment according to the child ratings and 81% compared with 30% according to the parent ratings.

Adverse Effects

Children and their parents in the CBT group were asked about their treatment experiences by a short qualitative interview after the treatment, and they did not report any adverse events. No adverse effects were spontaneously reported by the dental team or the psychologists who were part of the study either.

Discussion

Main Findings

CBT is an efficacious treatment for children and adolescents with dental anxiety according to our findings. CBT resulted in superior psychological treatment improvements compared with treatment as usual. At the 1-y follow-up, 73% of those in the CBT group managed all stages of the behavior avoidance test compared with 13% in the control group (including receiving local anesthesia and drilling). Furthermore, 91% in the CBT group compared with 25% in the control group no longer met the diagnostic criteria for dental anxiety at the 1-y follow-up. We chose a 1-y follow-up period because it is common in both CBT studies and in dentistry (1-y recall interval).

Effect sizes for both the CBT and controls regarding the BAT and CFSS-DS outcome measures were large, indicating that we achieved our aim of having treatment as usual as an active control group. The CBT group, however, showed a larger effect size than the control group. Treatment effects were maintained at the 1-y follow-up. One interesting finding was that the effect size related to self-efficacy was high for the CBT group and low for the control group. This, in addition to a significant increase in the SEQ-SP from before treatment to the after-treatment assessment and 1-y follow-up seen only in the CBT group, could support studies that suggest self-efficacy as a mechanism of change in CBT (Gallagher et al. 2013). Findings in the present study are consistent with results of CBT and its efficiency in treating children and adolescents with anxiety disorders (In-Albon and Schneider 2007; Davis et al. 2012).

According to repeated-measures ANOVA, interaction effects of time and group were nonsignificant for several secondary outcomes. This could be due to the absence of improvement from the after-treatment assessment to the 1-y follow-up for the CFSS-DS (C & P) and SEQ-SP. We did not offer patients booster sessions (since the controls could not get this intervention, and it would disrupt the randomized controlled trial design), which could explain the lack of improvement between the after-treatment assessment and the 1-y follow-up.

Most children and adolescents in our study stated that intraoral injection was one of their main fears in dentistry. This made the CFSS-DS inappropriate as the primary outcome measure, since it contains only 1 item measuring injection fear, and the literature suggests that the CFSS-DS cannot measure changes in the degree of injection fear properly (Lopes et al. 2013). Other reasons for choosing the BAT as our primary outcome included its greater capacity to reflect the child's actual performance in dentistry and that it can be measured by a blinded assessor, which increases accuracy and reduces detection bias.

The necessary dental treatment needs of participants in both intervention groups were met according to information from dental records. This suggest that treatment-as-usual methods such as sedation techniques make it possible for children with dental anxiety to undergo dental treatment in specialist pediatric dentistry. Our study shows that these methods in contrast to CBT cannot sufficiently influence the behavioral and emotional variables important for clinically significant and sustainable psychological change.

Limitations

This study is limited by the number of randomized patients, which may reduce the representativeness of the sample and create difficulties in generalizing the results. The reason for the small sample size in this study was difficulty in recruiting and finding participants who fulfilled the inclusion criteria and were willing to participate in a psychological scientific study. The individuals we invited to participate in the study were a mixed group of referred patients (from general dentists) that included patients with behavior management problems, dental fear, and primary psychiatric diagnoses other than dental anxiety. Some were receiving ongoing psychological treatment elsewhere, which led to their exclusion. Our inclusion criteria were, perhaps, too strict. But, since this is the first randomized controlled trial of CBT in pediatric dentistry, we aimed for high internal validity rather than high external validity. The literature recognizes the difficulties in recruiting participants with a specific phobia diagnosis in general and with dental anxiety in particular (Antony and Barlow 2002; Wide Boman et al. 2014). Another limitation is related to the use of treatment as usual as the control group. This meant that we could not match the number of dental visits in our intervention groups.

Implications

As stated in a recent meta-analysis, it is uncertain if methods commonly used in pediatric dentistry to manage dental anxiety can influence behavioral problems sufficiently (Mejàre et al. 2015).

The results of this study show that it is feasible to conduct CBT for children and adolescents with dental anxiety in dentistry. The treatment approach is effective in increasing a patient's ability to manage dental procedures, increase self-efficacy, and reduce fear related to specific dental procedures. Strengths of this study include its randomization, manual-based treatment, standardized masked BAT, and 4-fold measurement (child, parent, dentist, and psychologist assessments). Furthermore, the trial was conducted in a naturalistic real-world clinical setting, which suggests that the results could be an important and promising treatment alternative for children and adolescents with dental anxiety and should be made accessible for this patient group. Nevertheless, there is a need for more randomized controlled trials of CBT for children and adolescents in dental settings. There is also a need to modify and adapt CBT for dental organizations that do not have access to psychologists and for groups of patients in pediatric dentistry who cannot benefit from the traditional face-to-face version of the CBT treatment (e.g., patients and parents who cannot take time off from work or school to visit a psychologist). Studies examining the efficiency of shorter CBT interventions such as 1-session treatment would also be important to conduct in pediatric dentistry (Haukebø et al. 2008).

Author Contributions

S. Shahnavaz, contributed to conception, design, and data acquisition, drafted and critically revised the manuscript; E. Hedman, contributed to conception, design, data analysis, and interpretation, critically revised the manuscript; M. Grindefjord, contributed to conception, design, and data acquisition, critically revised the manuscript; L. Reuterskiöld and G. Dahllöf, contributed to conception, design, data acquisition, analysis, and interpretation, critically revised the manuscript. All authors gave final approval and agree to be accountable for all aspects of the work.

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